Laboratory Data Use Problem Statement

Created by the *Laboratory Data Use Task Group*
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Lab Data Use Task Group – Background

The California Privacy and Security Advisory Board (CalPSAB) was established by the Secretary of the California Health and Human Services Agency (CHHS). The CalPSAB mission is to develop and recommend privacy and security policies for California Health Information Exchange (HIE) that promote quality of care, respect the privacy and security of individual health information, and enhance trust. The CalPSAB's four committees; Privacy, IT Security, Legal, and Education, are responsible for analyzing issues, developing and evaluating the effectiveness of alternative solutions, and presenting recommendations to the CalPSAB.

In November of 2007, as part of the Privacy Committee's work, the Patient Consent for Health Information Exchange (HIE) Task Group was formed with the mission to define and evaluate the alternatives for individual consent to exchange health information in California. The Patient Consent for HIE Task Group advanced in their work with a progressive awareness of the need to place the consent options in context with specific scenarios, one of them being Laboratory. As each of the task groups processed through the consent options, growing insight into the need for two significant pieces of information emerged.

One piece that was needed to affirm a consent option was access control standards. It was deemed critically necessary to have the appropriate controls in place to manage access to the data before a patient could consent to the flow of their data in an HIE. The second piece that was needed was an understanding of secondary uses of information in the health care environment. In order to facilitate an HIE founded in privacy it was necessary to understand the flow of the data. Multiple Task Groups are operating or are planned to evaluate the secondary use of data in different health care scenarios including: ePrescribing; Laboratory; Emergency Department; Public Health; and others. The Laboratory Data Use Task Group was formed in March 2009.

Methodology

The Lab Data Use Task Group used a collaborative methodology to determine the flow of lab data and to identify any problems that may undermine a successful HIE environment that indoctrinates privacy throughout the flow of laboratory data. The Task Group represents a collaboration of public and private sector entities that interact with laboratory data as it flows through the health care environment. Included in the Task Group are state, county, hospital, laboratory, provider, and health plan representatives. The Lab Data Use Task Group members included:

- ✓ Brent Barnhart
- ✓ Joan Beach, Catholic HealthCare West
- ✓ Robert Folden, Catholic HealthCare West
- ✓ Dixie Gleason, Mendocino Community Health Center
- ✓ Tim Hamill, MD, University of California, San Francisco
- ✓ Teri Hearn, WellPoint

- ✓ Paul Kimsey, MD, California Department of Public Health
- ✓ Michelle Kirby, Catholic HealthCare West
- ✓ David Nelson, San Diego County
- ✓ Mike Hogarth, MD, University of California, Davis
- ✓ Will Ross, Mendocino Informatics
- ✓ Jim Sullivan, BearingPoint
- ✓ Kathleen Delaney-Greenbaum, California Office of Health Information Integrity
- ✓ Alan Roush, California Office of Health Information Integrity

Prior to convening as a group, research was compiled to create a preliminary view of the current Lab data use landscape. The research consisted of information provided on the internet as well as independent interviews with relevant parties. A diagram was then crafted to illustrate the flow of laboratory data and the entities involved. Once this information was prepared and assembled, the Task Group met using the following methodology:

- ✓ ***Review steps in the data flow*** – Each scenario step in the data flow was reviewed for accuracy in depiction by subject matter experts who represent the entities in the data flow. Missing steps in the flow were added where appropriate and inaccurate steps were corrected or removed from the data flow.

NOTE: Due to lack of task group representation, not all steps in the data flow were validated by individuals who represent an entity in the diagram, specifically, vendors (disease management, pay for performance, HEDIS, general healthcare), Center for Disease Control, biobanks, and both insurance industry and clinical trials actors.

- ✓ ***Review purpose of the data flow*** –The purpose of the data use was reviewed at each step in the data flow. Often times, at this point secondary use issues emerged as privacy needs, deficiencies in process, lack of standards, and other problems were discussed.
- ✓ ***Describe relationships for each step in the data flow*** – After each step was addressed for accuracy and purpose of data use, the set(s) of relationships between entities involved in each step of the scenario were reviewed. A step could have one set of relationships defined or multiple relationships depending on the complexity of data flow and the number of entities involved.
- ✓ ***Describe facilitators and barriers to the data flow*** – After the relationships were established, the facilitators and barriers to the flow of data were described. Legal analysis was prepared prior to the Task Group meeting to describe where data was allowed by law or contract to flow and where the data was not allowed to flow.
- ✓ ***Develop Problem Statement*** –The problems in the use of Laboratory data emerged from the Task Group discussions. A Problem Statement report was created to document each of the issues.

The Laboratory Context

There are a few key items discussed consistently through the task group meetings that provide the appropriate context for the 'issues' identified by the task group.

- Laboratory data travels – as the working diagram and worksheet show, laboratory data travels many places outside of the typical patient, physician, and laboratory relationship. It travels to expected places such as public health and unexpected places such as health plans, employer, and various vendors.
- Laboratory data is usually identifiable – during the travels described above, the lab data is almost always individually identifiable.
- Laboratory data is traveling more – lab results are continuously identified as criteria for public and private quality and performance measurement initiatives. This creates a demand for lab data beyond the typical treatment settings. In addition, the typical management of patient care by providers is being 'supported' increasingly by health plans, medical groups, and other vendors who therefore have a need for laboratory data to provide optimal care.
- Task Group focused on flow – the flow of lab data was the focus of this task group, not the mischievous use of data. As such, the issues identified required additional analysis to determine the true identification of an issue for this task group.

The Task Group acknowledged that the February 2009 Health Information Technology for Economic and Clinical Health Act (HITECH Act) includes provisions associated with privacy and security of health information. The new legislation has requirements, new enforcement provisions and penalties for covered entities, business associates, vendors and others. Although HITECH contains these specific provisions, subsequent clarifications and guidance by the federal government still need to be provided. Therefore, the problems addressed in this report were not set against the HITECH Act provisions. Future Task Groups will take a closer examination of the problems and will include HITECH Act provisions as part of the analysis. The information gathered in the Laboratory Data Use Task Group will be available to those future Task Groups.

Problem Findings

Five distinct problems related to secondary uses of Lab data emerged from the work of the Lab Data Use Task Group. Those problems are as follows:

1. Secondary Uses of Lab Data by Employers
2. Secondary Uses of Lab Data by Health Plans
3. Secondary Uses of Lab Data by Vendors (including BA's)
4. Secondary Uses of Lab Data for Research
5. Secondary Uses of Sensitive Lab Data

1. Secondary Use of Lab Data by Employers

Employers seek healthcare data, including lab results, to facilitate their management of healthcare costs. They receive lab results from Health Plans, Vendors, and

Laboratories. Both HIPAA and CMIA have limitations for uses of and disclosures of identifiable healthcare data to Employers. HIPAA's minimum necessary provisions do not apply to Employers because they are not HIPAA covered entities. De-identified data is permissible, however, literature reviews suggest that Employers receive identifiable healthcare data and analyze it to help manage their healthcare costs through benefit design modifications, or programs such as disease management, and wellness.

Some Employers also have onsite clinics that order and/or receive lab results. They are seen as a benefit for employees but may cause concerns regarding Employers' access to identifiable healthcare data. There needs to be clear evidence of a firewall between the clinic and the rest of the Employer to meet privacy requirements.

Self-insured Employers have more access to identifiable healthcare data for the purposes of managing their health/benefits plan. They can analyze the data for plan design; and also use it for programs like disease management and wellness.

Both CMIA and HIPAA state that identifiable healthcare data is not to be used for employment related decisions. Employers' concern and efforts to promote employee wellness are typically seen as positive, but it also becomes worrisome as it would not be evident if an employee was dismissed or suffered some other adverse event due to health care costs.

2. Secondary Uses of Lab Data by Health Plans

Health Plans gain access to identifiable healthcare data, including lab results, for multiple purposes, including quality, Pay for Performance (P4P), disease management, and others. For quality purposes, over 90 percent of Health Plans in America are required to and/or volunteer to be measured according to the National Committee on Quality Assurance (NCQA) Health Plan Employer Data and Information Set (HEDIS) measurement tool. The HEDIS tool increasingly identifies automated Lab results as the preferred method for evaluating certain measures; such as diabetes. The HEDIS reporting requirements increase justification for Health Plans to receive identifiable healthcare data including lab results. Health Plans in California also utilize data captured for HEDIS to facilitate P4P analysis.

Health Plans also collect lab results to facilitate or directly perform disease management programs. Identifiable healthcare data is utilized to identify targeted populations for specific programs and ongoing care management activities.

Identifiable healthcare data in the hands of Health Plans is expected to be for the benefit of the patient/member. However, as Health Plans increasingly participate in the management of patient care, it can appear that the financial motivations of the Health Plan may outweigh the benefits for the patient. Clear policies for Health Plans use of identifiable healthcare data is needed to facilitate trust in the HIE environment.

3. Secondary Uses of Lab Data by Vendors

There are many vendors participating in the healthcare environment assisting providers, Health Plans and others organizations. The analysis of Lab data usage shows that many receive identifiable healthcare data, including lab results. HIPAA and CMIA allow vendors to assist providers and health plans as long as certain conditions are met, such as business associate agreements.

Vendors assist Health Plans with disease management, HEDIS, P4P, and various other activities involving identifiable healthcare data, including Lab data. Because of their relationship with Health Plans, these vendors are subject to similar concerns regarding the competition between patient benefit and financial motivations.

Vendors assist providers with disease management, P4P, data analysis, chart reviews, and many other activities that involve identifiable health care data, including lab results. Providers and Labs also rely on vendors for information systems and ongoing maintenance, support, etc. Their access to identifiable healthcare data with commercial value creates opportunity for inappropriate use and/or disclosure of this data.

It is not obvious to the Task Group that all relationships between vendors and Health Plans and providers are covered by appropriate business associate agreements. Appropriate business associate agreements for each relationship are needed to ensure the privacy of identifiable healthcare data.

4. Secondary Uses of Lab Data for Research

Clinical Trials are conducted within a regulatory framework established by the Food & Drug Agency (FDA) which allows Institutional Review Boards (IRB) to waive HIPAA authorization requirements. IRBs are the entities responsible for protecting the rights (including patient confidentiality) and welfare of research subjects; however, there have been concerns in the industry regarding the operation and oversite of IRBs. The FDA occasionally takes oversight action - in April 2009, the FDA imposed restrictions on an IRB overseeing over 300 active studies because is could not protect the rights and welfare of human research subjects.

The definition of research has also been a concern for the Task Group because it allows significant amounts of identifiable healthcare data to be collected. HIPAA expects research to be designed to develop or contribute to generalizable knowledge. In addition, the differences between research and other investigatory analysis are not always clear, which occasionally causes confusion between IRBs and covered entities.

The Task Group believes that additional clarification into research is needed to provide clear guidance for the HIE environment. A white paper or guidelines regarding 1) use and disclosure of identifiable healthcare data for research vs. other investigatory analysis; and 2) appropriate interactions with IRBs; would facilitate appropriate research and ensure privacy protections in the HIE environment.

5. Secondary Uses of Sensitive Lab Data

During Task Group review of public health reporting it was noted that special reporting requirements exist for Lab reports for HIV infections. These reports are required to be sent from the lab to the local health department by traceable mail or person-to-person transfer only; use of fax, email or non-traceable mail is not permitted. The Task Group believes that transfer via an HIE would also not be permitted.

The Task Group also recognized that the Genetic Information Nondiscrimination Act of 2008 (GINA) that will protect Americans against discrimination based on their genetic information when it comes to health insurance and employment may impact the discussion of privacy in the HIE environment.

Other Items of Interest

During Task Group discussions, numerous topics arose that don't quite rise up to the scale of the five issues documented above. These are more items of interest that the Task Group wants noted for potential follow-on activities:

- Personal Health Records (PHR) – The Task Group noted that there are a wide variety of systems that may be considered PHRs. In some cases, lab test data entered into a PHR may be utilized by providers. Due to the defined scope of the Lab Data Use Task Group and the limited experience with PHRs, they are not represented within our data flow diagram and are not defined as receivers or senders of Lab data. The Task Group anticipates that PHRs will have a role in the HIE environment, but did not address this subject in this Task Group.
- Paper-based processes – The Task Group noted that many of the processes in the Lab environment are currently paper-based. Lab orders and results are often exchanged on paper or over the fax machine. The Task Group recognizes that the transition from largely paper-based process to electronic exchanges will be challenging for portions of the healthcare industry.
- Health Information Organization (HIO) role in Health Information Exchange (HIE) – The Task Group adopted the federal Office of National Coordinator of Health Care (ONC) definitions for HIO[1] and HIE[2] but did not establish the HIO as a participant in the data flow diagram. The Task Group recognized that the HIO is obviously critical to the operation of the HIE and will facilitate the exchange of information between many of the organizations reflected in the lab data flow diagram.

[1] An organization that oversees and governs the exchange of health-related information among organizations according to nationally recognized standards.
[2] The electronic movement of health-related information among organizations according to nationally recognized standards.

Conclusion

Secondary use of identifiable laboratory data is widespread and increasing. As California continues in the direction of HIE adoption, more electronic laboratory data will become readily available and more and more entities will want to access and use these data for multiple purposes. The Lab Data Use Task Group identified five distinct areas of privacy concern when looking specifically at secondary uses of Laboratory data. These issues need to be addressed to ensure trust in California's HIE.

Next Steps

The intent of the Task Group's *Laboratory Data Use Problem Statement Report* is to support the next phases of secondary use work. It will be assessed along with the Problem Statement Reports from the ePrescribing, Emergency Department, Public Health, Mental Health, Telemedicine, and Personal Health Record Task Groups. It is assumed that each Task Group will generate its own set of problems for the specific scenario they are examining. Where there are overlaps in problems, there will be a harmonization of the issue in order to avoid duplicative efforts.

A joint task group will then be assembled to explore a deeper understanding of each of the secondary use problems, including a closer look at the purpose of the data use, the limitations of its use, the privacy interests of those using the data, and the harms that may occur to an individual whose data is being used. Ultimately, the group will construct alternatives to resolving each of the problems.